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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,936	07/03/2001	Paul DiCarlo	BSI-479US	1985

7590 05/21/2004

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EXAMINER

LANDREM, KAMRIN R

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/898,936	DICARLO, PAUL	
Examiner	Art Unit	
Kamrin R. Landrem	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 25-27 and 35-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 25-27 and 35-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 9, 11, 15,25-27,36,38,42-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Balbierz et al (USPN 5,964,744).

With reference to Figure 4, Lentz discloses a prosthetic component 10 comprising a vascular graft (3:4) having proximal 14 and distal 16 ends. Hems 20 and 21 are disposed on ends 14 and 16. Lentz further discloses a stent 28 that is disposed within hems 20 and 21 of graft 10. Lentz discloses the method of implanting the prosthetic component (4:43+). Lentz discloses the claimed prosthetic however Lentz fails to disclose a cord disposed within the hems that is capable of absorbing fluid and expanding to aid in retention of the prosthesis within the body lumen. Balbierz teaches in Figure 12 cord shaped stent comprising a coated (10:46-48) polymer material that is physiologically acceptable (1:15-24) that upon hydration is capable of expanding to a predetermined shape to aid in retention. (7:46-57) Therefore, in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the polymer material as taught by Balbierz into the hems of the prosthesis disclosed by Lentz in order to produce a prosthesis that is capable of expanding and fixating securely against the walls of a body lumen.

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It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to perform. It does not constitute limitation in a patentable sense. In re Hutchinson, 69 USPQ 138. In this case since the reference structurally meets the claim it is fully capable of performing the function.

With regards to newly added claims 44-52, the Examiner directs the applicant's attention to (12:30-67) wherein Balbierz teaches that the stent material is made from a hydrophilic material that is capable of absorbing fluid and swelling (expanding) as a result of the absorption of water. The amount of swelling is controlled by the material content to allow the stent material to expand the initial cross ureteral stent outer diameter to a desired extent.

Claims 6,7, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Balbierz et al.

As disused above, Lentz as modified by Balbierz discloses the claimed device for implantation into a body lumen. Lentz as modified does not expressly disclose the flat-ribbon shape or the thickness of the cord. At the time the invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have made the cord of a thin flat shape to place into the hems of the graft prosthesis because the applicant has not disclosed that a cord that is less than thirty thousandths of an inch thick and has a flat ribbon shape provides an advantage, is used for a particular purpose, or solves a staged problem. One of ordinary skill in the art, further more, would have expected Applicants invention to perform equally well with the circular shaped device as taught by Balbierz because it is capable of being placed within the hems of the prosthesis disclosed by Lentz and expanding upon contact with bodily fluids to provide a secure attachment to the body lumen.

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Claims 10, 14, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz as modified by Balbierz further in view of Solovay (USPN 5,769,884).

As discussed above, Lentz as modified by Balbierz discloses the claimed device for implantation into a body lumen. Lentz however does not disclose variable porosity or permeability of the device. With reference to Figures 6-6E Solovay teaches a device for placement into a body lumen that has variable pore size and permeability to allow for healthy tissue and capillary ingrowth near the ends of the stent (2:13+). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have increased the porosity in the area of the hems to provide increased permeability for fluid expansion of the cord and to increase healthy tissue ingrowth thus providing additional support of the device within the lumen of the body.

Claims 12, 13, 35, 39, and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz as modified by Balbierz, further in view of Lauterjung (USPN 5,824,036).

As discussed above, Lentz as modified by Balbierz discloses the claimed device for implantation into a body lumen. Lentz however does not disclose a stent placed within the graft device that extends protrudes distally from the graft device. With reference to Figure 3 Lauterjung teaches a stent graft combination comprising a stent 154 contained within a graft 112 with portions 156 extending away from the end of the graft for anchoring the graft to the inside of the lumen and thereby assist in holding the device assembly in place (4:10-15). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device disclosed by Lentz by incorporating an inner

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stent that extends before the end of the graft to provide further anchoring and support for the luminal device.

Response to Arguments

Applicant's arguments filed 3/15/2004 have been fully considered but they are not persuasive. With reference to applicant's argument concerning the motivation to combine Lentz and Balbierz, contrary to applicant's arguments, Balbierz does teach in multiple places (abstract. 1:20-25, 2:19-23, 3:36-47, 17:46-52) the insertion or implantation of a device followed by expansion of the device in order to be retained without expulsion from a body cavity. Balbierz further teaches that this can also be applied to blood vessel stents, feeding tubes, aneurysm shunts, stenosis dilators, etc. (1:48-61). Therefore Balbierz is used to teach a cord-like material capable of expanding and providing retention means. The Examiner did provide motivation to combine Lentz and Balbierz in Paper No. 10. Applicant's newly added claims have been addressed within the body of the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
AU 3738

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